

## **REMARKS/ARGUMENTS**

### **I. Status of the Claims**

Claims 1-15 remain in this application. Claims 16-53 have been canceled. In view of the examiner's earlier restriction requirement, applicant retains the right to present claims 16-53 in a divisional application. Claim 1 has been amended recite that the sensory regimen comprises at least two stimuli selected from the group consisting of auditory stimuli, visual stimuli, tactile stimuli, gustatory stimuli and olfactory stimuli. Support for the amendment to claim 1 can be found in the specification at least at page 7, 4<sup>th</sup> paragraph and page 10, 2<sup>nd</sup> paragraph.

### **III. Claim Rejections – 35 U.S.C. § 102**

The Examiner has rejected claims 1-4, 8, 9, 14 and 15 as allegedly anticipated by U.S. Patent No. 5,753,637 ("Fried"). Applicants respectfully traverse this rejection.

Applicants claimed invention relates to a method for reducing the number and severity of acne lesions on the skin of a mammal. The method comprises the step of administering a sensory regimen in an amount effective to downregulate the activity of the HPA axis of said mammal in combination with the administration of an anti-acne composition comprising an effective amount of an anti-acne agent. The sensory regimen comprises at least two stimuli selected from the group consisting of auditory stimuli, visual stimuli, tactile stimuli, gustatory stimuli and olfactory stimuli, and combinations thereof and is effective to downregulate the activity of the HPA axis and wherein said activity of the HPA axis is downregulated by at least one of the following methods: (1) reducing the amount of total daily adrenocortical hormone; (2) reducing adrenocortical hormone at any time point in the period from about 4 to about 8 hours following morning waking; (3) reducing the total daily adrenocortical hormone minus the integrative measure of morning peak adrenocortical hormone.

It is the Examiner's position that Fried teaches the inclusion of aloe vera gel in acne compositions and therefore anticipates the present claims. Applicants respectfully disagree. Fried teaches that aloe vera gel is an "inert carrier." See col. 2, lines 56-65. Indeed, Fried specifically states that "particular blends of carriers are not critical to the present invention, as long as they provide no interference with the activity of the acne treatment medication and the vasoconstrictor, and hence, are inert." See col. 3, lines 5-8. Accordingly, Fried

specifically teaches that aloe vera gel does not have any effect on the activity of the acne treatment. Fried makes no mention of a sensory regimen which is effective to downregulate the activity of the HPA axis. The “inert carriers” which are “not critical” and “provide no interference” taught by Fried would simply not be effective to downregulate the activity of the HPA axis. Accordingly, Fried fails to anticipate the claimed invention.

Further, Fried simply relates to a method for treating acne conditions comprising an acne treatment medicine with is benzoyl peroxide. There is no teaching or suggestion in Fried of a method for reducing the number and severity of acne lesions on the skin of a mammal comprising the step of administering a sensory regimen comprising at least two stimuli selected from the group consisting of auditory stimuli, visual stimuli, tactile stimuli, gustatory stimuli and olfactory stimuli, and combinations thereof, much less, that the sensory regimen is effective to downregulate the activity of the HPA axis and wherein said activity of the HPA axis is downregulated by at least one of the following methods: (1) reducing the amount of total daily adrenocortical hormone; (2) reducing adrenocortical hormone at any time point in the period from about 4 to about 8 hours following morning waking; (3) reducing the total daily adrenocortical hormone minus the integrative measure of morning peak adrenocortical hormone. Accordingly, Fried fails to anticipate the present claims.

#### **IV. Claim Rejections – 35 U.S.C. § 103**

The Examiner has rejected claim 7 as allegedly unpatentable over Fried in view of U.S. Patent No. 5,466,446 (“Stiefel et al.”). The Examiner relies upon Stiefel et al. for teaching the motivation of adding an antibacterial composition to the compositions of Fried. Applicants respectfully traverse this rejection at least for the reasons set forth above with respect to Fried, as Stiefel does not remedy the deficiencies of Fried.

#### **V. Conclusion**

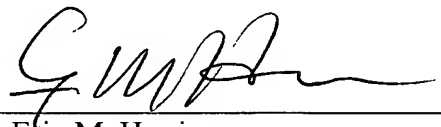
Applicants believe that the foregoing presents a full and complete response to the outstanding Office Action. An early and favorable response to this Amendment is earnestly solicited. If the Examiner feels that a discussion with Applicants’ representative would be helpful in

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resolving the outstanding issues, the Examiner is invited to contact Applicants' representative at the number provided below.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/JBP-571/EMH. If a fee is required for an Extension of time 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

By:   
Erin M. Harriman  
Reg. No. 40,410

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-3619  
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